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Supreme Court, U.S.

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No. 96-188

In The
Supreme Court Of The United States
OCTOBER TERM, 1996

GENERAL ELECTRIC COMPANY,
WESTINGHOUSE ELECTRIC CORPORATION, and
MONSANTO COMPANY,
Petitioners,
v.

ROBERT K. JOINER and KAREN P. JOINER,
Respondents.

On Writ Of Certiorari
To The United States Court of Appeals
For The Eleventh Circuit

**MOTION FOR LEAVE TO FILE BRIEF *AMICI CURIAE*
AND BRIEF *AMICI CURIAE* OF BRUCE N. AMES,
MICHAEL GOUGH, ARTHUR M. LANGER, RODNEY
NICHOLS, FREDERICK SEITZ, ARTHUR CANFIELD
UPTON AND RICHARD WILSON IN SUPPORT OF
PETITIONERS.**

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MOTION FOR LEAVE TO FILE BRIEF AMICI CURIAE

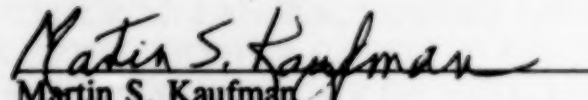
Pursuant to Rule 36 of the Rules of the Supreme Court, Atlantic Legal Foundation ("ALF") moves this Court for leave to file its brief *amicus curiae* (bound with this motion) on behalf of seven distinguished scientists in support of the ruling of the district court below with respect to the admissibility of plaintiffs' experts' scientific evidence.

Amici believe that they can contribute pertinent and helpful discussion to this Court's understanding of this case. Several of the *amici* appeared before this Court as *amici* in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). *Amici* have no axe to grind but rather are interested only in seeing that proper scientific methodology prevails. In that context *amici* will argue that plaintiffs' expert witnesses failed to use proper scientific methodology and analysis and therefore the district court's decision to exclude their evidence as unreliable was correct.

Amici did not seek the consent of the parties in an effort to maintain their neutral posture. *Amici* pray that this Court grant their motion for leave to file the accompanying brief *amici curiae*.

DATED: New York, New York: May 29, 1997

Respectfully submitted,
Atlantic Legal Foundation
By its attorneys,


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Letters from all parties consenting to the filing of this brief have been filed with the Clerk of this Court.

Pursuant to Supreme Court Rule 37.6, *amici curiae* state that this brief was not prepared, written, funded or produced by any person or entity other than *amici curiae* or their counsel.

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TABLE OF CONTENTS

	PAGE
TABLE OF AUTHORITIES	ii
INTEREST OF <i>AMICI</i>	3
SUMMARY OF ARGUMENT	9
ARGUMENT	9
SCIENTIFIC EVIDENCE MUST BE RELIABLE	9
A. To Be Admissible Under <i>Daubert</i> Scientific Evidence Must Be Reliable	9
B. The Evidence of Plaintiffs' Scientific Experts Is Not Reliable	11
CONCLUSION	20

TABLE OF AUTHORITIES

CASES

PAGE

<i>Daubert v. Merrell Dow Pharmaceuticals</i> , 509 U.S. 579 (1993)	3, 9, 10, 11
<i>Turpin v. Merrell Dow Pharmaceuticals</i> , 959 F.2d 1349 (6th Cir. (Cert. denied), 506 U.S. 826, 113 S.Ct. 84, 121 L.Ed. 2d 47 (1992)	11, 19
<i>Brock v. Merrell Dow Pharmaceuticals</i> , 874 F.2d 307 (5th Cir. 1989), <i>Modified</i> , 884 F.2d 166 (5th Cir. 1989), <i>Cert. denied</i> , 494 U.S. 1046, 110 S.Ct. 1511, 108 L.Ed. 2d 646 (1990)	11

ARTICLES and STUDIES

Bertazzi, et al., <u>Cancer Mortality of Capacitor Manufacturing Workers</u> 11 Am. J. Indus. Med. 165 (1987)	12, 13
Judith A. Zack and David C. Musch, "Mortality of PCB Workers at the Monsanto Plant in Sauget, Illinois" (1979)	13
Ikeda, et al., <u>A Cohort Study on Mortality of Yusho Patients - A Preliminary Report</u> , 78 Fukuoka Acta Med. 297 (1989)	13
Environmental Protection Agency, "PCBs: Cancer Dose - Response Assessment and Application to Environmental Mixtures", Wash. D.C. U.S.EPA, 1996 [EPA/600/P-96/001F]	16, 18

INTEREST OF AMICI

Amici are scientists, scholars, and teachers of science. Some are recipients of distinguished prizes and awards in their fields. The fields of expertise of *amici* include chemistry, biochemistry, physics, medicine, epidemiology and environmental medicine. Some are or were editors and contributors to scientific and other scholarly journals, and are authors of authoritative works in their respective areas of expertise. Most of *amici* are professors at several of the most highly regarded institutions of higher education in the United States, and one is the former president of one of the most prestigious research universities in the world. *Amici* hold other distinctions for achievements in fields of science and academia. *Amici* are authors of numerous articles, studies, monographs and textbooks. Some are frequently called upon to serve on official commissions, review boards, advisory committees and institutes.

Some of the *amici* previously submitted their views on the nature of scientific knowledge and the methods and procedures of science and the interaction between science and jurisprudence in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993).

Amici have no interest in the outcome of this case or any other "PCB case." They appear solely as individuals, on their own behalf, to inform the Court of their views as to the appropriate criteria for acceptable scientific evidence, and to argue briefly why the District Court was correct in declining to

admit the plaintiffs' experts' testimony into evidence because it was methodologically flawed and scientifically unreliable. Their interest transcends the issues in this case and the positions of any party.

BRUCE N. AMES is Professor of Biochemistry and Molecular Biology at the University of California in Berkeley, California and was chairman of that department from 1983 - 1989. Dr. AMES received his B.A. from Cornell University in 1950 and his Ph.D., with a biochemistry major, from the California Institute of Technology in 1953. He served from 1954-1960 as a biochemist at the National Institutes of Health. Dr. AMES has received a number of awards, including the Charles S. Mott prize from the GM Cancer Research Foundation, the Gold Medal from the American Institute of Chemists, the Society of Toxicology Public Communications Award and the Wadsworth Award, among others. In 1976 he received a Presidential Appointment from the National Cancer Advisory Board. He served on the Consultative Panel on Hazards of Chemical Pesticides, National Research Council, National Academy of Sciences. He served on the President's Biomedical Research Panel. Dr. AMES has received a number of honors and awards, including membership in the American Academy of Arts and Sciences and the National Academy of Sciences and honorary degrees from Tufts University and the University of Bologna. He was elected a Fellow of the Academy of Toxicology Sciences and a Fellow of the American Academy of Microbiology. He has been the author of over 370 scientific publications and was the 23rd most-cited scientist (in all fields) 1973-1984.

MICHAEL GOUGH is the Director of Science and Risk Studies at the CATO Institute in Washington, DC. Dr. Gough received his B.A. degree in biology from Grinnell College in 1961 where he was a George C. Baker National Scholar and his Ph.D. in Biology from Brown University in 1966. He has taught microbiology at Baylor College of Medicine and the State University of New York. He also served as the Manager of the Biological and Behavioral Sciences Program in the Office of Technology Assessment, U.S. Congress. Dr. Gough was elected Fellow of the Society for Risk Analysis in 1996. He has served on a number of scientific panels and committees, including the Dioxin Reassessment Review Committee of the Science Advisory Board of the U.S. Environmental Protection Agency, Chair of the Advisory Committee on the Health-Related Effects of Herbicides, U.S. Department of Veteran Affairs, Consultant to the Science Advisory Board of the Environmental Protection Agency and member of the Agent Orange Advisory Panel and Advisory Panel on Health Effects Studies in Atomic Veterans of the Office of Technology Assessment. Dr. Gough has written numerous papers and articles and given congressional testimony a number of times about subjects ranging from biotechnology, Agent Orange, dioxin and environmental causes of cancer to such specialized topics as pesticide safety.

ARTHUR M. LANGER is the Director of the Environmental Sciences Laboratory of the Institute of Applied Sciences and Professor of Geology at Brooklyn College of the City University of New York. He was Associate Professor in the Center for Polypeptide and Membrane Research at the Mt.

Sinai School of Medicine in New York and Associate Professor of Mineralogy at Mt. Sinai. He has been an editor and member of the editorial board of several scientific journals including *Environmental Research*, *American Journal of Industrial Medicine*, *Journal of Environmental Pathology and Toxicology* and *Journal of Environmental Pathology, Toxicology and Oncology*. He has served on numerous government and international organization committees and consultative groups including the International Agency for Research on Cancer, The United States Food and Drug Administration, the United States Environmental Protection Agency and the National Institute for Occupational Safety and Health. He has published over 60 articles in peer-reviewed journals as well as numerous symposia proceedings, monographs and abstracts.

RODNEY NICHOLS is President and Chief Executive Officer of the New York Academy of Sciences. He has been a member of the Executive Committee of the Carnegie Commission on Science, Technology and Government and was the principal author of the Commission's report "Science and Technology in U.S. International Affairs" (1992). He is a member of the National Academy of Sciences Committee on International Organizations and Programs. He is the chair of the Committee on Science and Technology in Developing Countries of the International Council of Scientific Unions.

FREDERICK SEITZ is President Emeritus of The Rockefeller University, a leading research institution. In addition to an earned Ph.D. in physics, he has been awarded 30 honorary degrees from such institutions as Princeton

University, Northwestern, University of Michigan, Brown, NYU and University of Pennsylvania. He has received numerous awards for his work as a scientist and educator including the National Medal of Science (1973), the Franklin Medal (1965), the Department of Defense Distinguished Service Award (1968), the Nassau Distinguished Service Award (1969) and the American College of Physicians Edward R. Loveland Memorial Award (1983). He served two terms as president of the National Academy of Sciences and has been Chairman of the Board of the Sloan-Kettering Institute for Cancer Research. He has served on numerous government and academic boards, councils and committees, including the President's Science Advisory Committee, the National Cancer Advisory Board, the Naval Research Advisory Committee and the Advisory Council of the Smithsonian Institution. He has been a member of the boards of trustees of numerous universities and is a member of many United States and foreign scientific academies. He is an editor or a member of the editorial board of numerous scientific publications.

ARTHUR CANFIELD UPTON is Clinical Professor of Environmental and Community Medicine, UMDNJ-Robert Wood Johnson Medical School and also Clinical Professor of Radiology, University of New Mexico School of Medicine. Dr. Upton received his B.A. from the University of Michigan in 1944 and his M.D. from the University of Michigan in 1946. Dr. Upton has also served as Chief of Pathology-Physiology Section, Oak Ridge National Laboratory and Chairman of the Department of Pathology at the State University of New York at Stony Brook. He was also a

Director of the National Cancer Institute from 1977-1979. Dr. Upton has written over 300 published articles, books and reports on radiation injury, carcinogenesis, and environmental toxicology. He is, or has been, a member of the Board of Directors of the Society for Experimental Biology and Medicine, the Society for the Study of Comparative Oncology and the International Consortium for Research on the Health Effects of Radiation. He has also been President of the American Association for Cancer Research, the American Society for Experimental Pathology and the Radiation Research Society.

RICHARD WILSON is Mallinckrodt Professor of Physics at Harvard University, Director of the Regional Center for Global Environmental Change at Harvard University, Affiliate of the Center for Science and International Affairs and the Center for Middle Eastern Studies at Harvard University. He is a past Chairman of the Department of Physics at Harvard University, a past chairman and currently a member of the Cyclotron Operating Committee. He is a member of numerous committees and is consultant to numerous government and academic institutions including the Physics Advisory Board of the National Science Foundation, a member of the Breeder Reactor Safety Committee of the Energy Research and Development Administration, a consultant to the Los Alamos, Oakridge and Lawrence Livermore laboratories, chairman of the Visiting Committee on Radiation Medicine, Massachusetts General Hospital and Director of the Sakharov Foundation. He is a fellow or member of the American Physical Society, the American Academy of Arts and Sciences and the Society for

Physical Research (London). He is the author or editor of over 500 articles, book chapters and other works.

SUMMARY OF ARGUMENT

Scientific evidence to be admissible under *Daubert* must be relevant and reliable. The evidence of plaintiffs' experts was not reliable because they failed to follow proper scientific methodology and failed to bridge the analytical gap between their opinions and the particular facts of the case.

ARGUMENT

SCIENTIFIC EVIDENCE MUST BE RELIABLE.

A. *To Be Admissible Under Daubert Scientific Evidence Must Be Reliable*

This case offers the Court an opportunity to illuminate its ground-breaking ruling in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). In *Daubert*, this Court, by examining and applying the Federal Rules of Evidence, articulated a more flexible and sophisticated standard for the admissibility of expert scientific evidence than had theretofore been applied in the federal courts. See, e.g., *Daubert*, 509 U.S. at 588, 589. This Court amplified Rule 702's requirements as follows:

Faced with a proffer of expert scientific testimony ..., the trial judge must determine at the outset, pursuant to Rule 104(a), whether the

expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue. This entails a preliminary assessment of whether the reasoning or methodology underlying the testimony is scientifically valid and of whether that reasoning or methodology properly can be applied to the facts in issue.

Daubert, 509 U.S. at 580 (footnotes omitted).

While it is apparent that this Court intended by its decision in *Daubert* to depart from "rigid" and inflexible, almost talismanic, reliance on one criterion to determine admissibility, it is equally clear, we submit, that the thrust of *Daubert* was to recognize the "gatekeeper" role of federal trial judges, empowering them to enforce "limits on the admissibility of purportedly scientific evidence" and to "ensure that any and all scientific testimony or evidence that is admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 592. This Court in *Daubert* emphasized that the primary criteria to be used in determining admissibility are relevance and reliability. That reliability is to be a desideratum of admissibility is made clear, we believe, in the passage in which the Court addressed the concerns of the respondent and some *amici* in *Daubert* that the "abandonment of 'general acceptance' as the exclusive requirement for admission" would result in juries being "confounded by absurd and irrational pseudoscientific assertions," and sought to allay those fears by emphasizing the "conventional devices available to the court in directing a

verdict or granting summary judgment, citing with apparent favor *Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. ----, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992) and *Brock v. Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307 (5th Cir. 1989), *modified*, 884 F.2d 166 (CA5 1989), *cert. denied*, 494 U.S. 1046, 110 S.Ct. 1511, 108 L.Ed.2d 646 (1990)¹.

If, as we believe, the most significant lesson of *Daubert* is that it is important to prevent "pseudoscience" from distorting the legal process, then we submit that this case exemplifies a misreading by the Court of Appeals of *Daubert* and a proper application of *Daubert* by the District Court.

B. *The Evidence of Plaintiffs' Scientific Experts Is Not Reliable*

The central issue raised in the case at bar is what standard of review should an appellate court apply in reviewing a trial court's ruling on the admissibility of scientific evidence. We do not intend to comment on that issue other than to conclude that, regardless of what standard is applied, the district court was correct in denying the admissibility of

¹ In *Daubert* this Court stated,

Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it. Because of this risk, the judge in weighing possible prejudice against probative force under Rule 403 ... exercises more control over experts than over lay witnesses.

Daubert at ----, 113 S.Ct. at 2798.

plaintiffs' experts' testimony.

There is, however, an underlying issue, namely whether the evidence proffered by the plaintiffs' scientific experts was reliable. We submit that it was not.

The ultimate question is whether Mr. Joiner's small-cell lung cancer was caused or promoted by his exposure to PCBs.

Plaintiffs' own experts conceded that there are no studies which show that PCBs cause small cell lung cancer in humans. (Teitelbaum deposition at pp. 110-111).

Plaintiffs' experts, however, referred to four epidemiological studies on which they relied despite the fact that none of these studies supports the proposition that Joiner's small cell lung cancer was caused by PCBs.

First, plaintiffs offered "selected quotes" from Bertazzi, et al., Cancer Mortality of Capacitor Manufacturing Workers, 11 *Am.J.Indus.Med.* 165 (1987). The Bertazzi study concludes, however, that:

There were apparently no grounds for associating lung cancer deaths (although increased above expectations) and exposure in the plant. The numbers were small, the value of the risk estimate was not statistically significant, and such risk had never been suggested before.

864 F.Supp. at 1324, quoting Bertazzi, et al., "Cancer Mortality of Capacitor Manufacturing Workers," 11 *Am.J.Indus.Med.* 165, 172 (1987).

Plaintiffs also offered selected passages from Judith A. Zack & David C. Musch, "Mortality of PCB Workers at the Monsanto Plant in Sauget, Illinois" (1979), an unpublished study that Monsanto funded. This study was subsequently superseded by a later version which held that "while many of the cancer-specific [standardized mortality ratios] exceed 100, none [is] statistically significant." *Joiner v. General Electric Co.*, 864 F.Supp. 1310, 1325.

Plaintiffs assert that "[a]nother study of interest is a study of PCB exposed workers in a Norwegian cable manufacturing company. A statistically significant excess of deaths from lung cancer was observed. Ten deaths from lung cancer were observed when only 3.9 were expected." (Plaintiffs' Brief below at 13.) That study, however, "never mentions PCBs and does not involve 'PCB-exposed workers.'"

The last study Plaintiffs cite is Ikeda, et al., A Cohort Study on Mortality of Yusho Patients--A Preliminary Report, 78 *Fukuoka Acta Med.* 297 (1987), which Plaintiffs assert was summarized in a publication entitled World Health Organization's International Programme on Chemical Safety. Polychlorinated Biphenyls and Terphenyls 449 (2d Ed.1993). The "Yusho" incident involved Japanese people who were accidentally exposed to toxic substances. The report states that "[a] statistically significant excess mortality was seen for

malignant neoplasms, cancer of the liver and cancer of the lung, trachea, and bronchi in males.'" (Plaintiffs' Brief below at 13.)

As defendants correctly observed:

The [Ikeda] report was published in English by Kuratsune, et al., "Analysis of Deaths Seen Among Patients With Yusho--A Preliminary Report," Chemosphere, Vol. 16, Nos. 8/9, pp. 2085-2088 (1987). As indicated by the title, it is a "preliminary report" of an "analysis of deaths," not an epidemiological study. No regression analysis was done and the authors did not control for cigarette smoking, asbestos exposure, or other causes of cancer. Most significant, however, is the fact that, although the deaths were observed in Yusho patients, the authors did not examine if the observed excess risks might be related to the intake of toxic rice oil. Kuratsune, p. 2087. (Defendants' Brief below at 10 [emphasis in original].)

One of plaintiffs' expert witnesses, Dr. Arnold Schechter, acknowledged that the omission regarding toxic rice oil was significant:

A. ... We have a voluminous data on human response in Yusho and Yuchem to humans exposed to PCBs, dibenzofurans and dioxins.

Q. Now, in those two incidents, the Yusho and Yuchem, in both of those [incidents], what was the concentration of PCBs, was it a 65 percent concentration, was it 650 parts per million Aroclor or some equivalent?

A. I don't remember what it was. It was PCB and dibenzofuran and dioxin contamination of rice oil which was used to cook food. I don't think anyone can be certain of what the intake was. (Schechter DEP. at 91 [emphasis added].)

Finally, Dr. Daniel Teitelbaum, the other plaintiffs' expert, did not find much significance in the Yusho report:

Q. ... What, if any, epidemiological studies have you reviewed in reaching your opinion?

A.

... You've got Kuratsune's studies from Japan. You've got a few cases of lung cancer there. They're not very convincing, as the Japanese lifestyle is different. There's--it's, again, suggestive but not convincing. (Teitelbaum DEP. at 89-90.)

The limitations in the Yusho study (e.g., failure to investigate exposure to other potential carcinogens), the fact that the persons studied were exposed to furans

and dioxins, and the fact that one of Plaintiffs' own experts had a low opinion regarding the relevance of the Yusho study together combined to convince the district court that the study has no utility for Plaintiffs' purposes.

The District Court properly rejected the plaintiffs' experts' reading of epidemiology studies. They drew conclusions from results that were not statistically significant, ignoring the scientific tenet that such results are not accepted as convincing because of the high likelihood they arose by chance. The plaintiffs' experts produced no scientifically acceptable evidence that demonstrates increased lung cancer incidence in workers with known, high PCB exposures. They ignored the many published studies of PCBs that have failed to demonstrate a connection between PCB exposures and lung cancers. See list of six occupational epidemiological studies cited at pp. 8-10 of Environmental Protection Agency, "PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures", Wash.D.C. U.S.EPA, 1996 [EPA/600/P-96/001F].

The majority of epidemiology study results relevant to the proposition at issue here come from the experience of workers employed in the manufacture of PCB-containing electrical equipment, especially capacitors. These populations show two significant characteristics for the purpose at issue here: the incidence of lung cancer is not significantly greater in them than in the general public and they carry in their blood and fat significantly larger amounts of components of these fluids than do the general public, sometime a hundred times as

much.²

To draw reliable inferences from a series of epidemiology studies it is important to consider all relevant study results, weighting each result by its relevance and soundness. It is not scientifically appropriate to cite results of one or two studies that support one's preconceptions.

The Plaintiff's experts point to two experiments that they insist show the cancer causing potential of PCBs. Both experiments involved injecting suckling mice with 100 percent solutions of PCBs. In both experiments, the mice were exposed to an "initiator," a substance that can initiate the sequence of events that lead to cancer. In one experiment, injections of PCBs were made into the peritoneum of the mice; in the other, the injections were made directly into the stomach. Mice in both experiments did not develop small-cell lung cancer, admittedly Mr. Joiner's disease.

Animal studies are much less reliable than human studies or epidemiological studies when seeking to prove that exposure to some substance causes or produces cancer or some other disease in humans. Second, the particular animal studies relied on by plaintiffs' experts were not reliable. Indeed, the experts made telling concessions that undermined the tests' reliability. As the district court noted, plaintiffs' experts conceded that (1) the lung cancer in the mice exposed to PCBs

²The concentration of PCBs in Mr. Joiner's body was less than "background". There is no indication that he was highly exposed. Indeed, there is no evidence that he was more exposed than members of the non-occupationally exposed population.

was not small-cell carcinoma, the type that Mr. Joiner developed; (2) they did not know if the cancer that was detected in immature mice would also be found in mature mice exposed to PCBs; (3) the tumors were dose-related; (4) before being exposed to PCBs, the mice were injected with a known cancer initiating substance and then injected with a 100% solution of PCBs directly into the abdominal cavity or the stomach itself; and (5) the results of the studies were preliminary only. 864 F.Supp. at 1322-24.

Moreover, the fluids to which the plaintiff claims exposure have in fact been tested in more conventional rodent studies. These tests showed no increase in the lung cancer rate. *See*, Environmental Protection Agency, "PCBs: Cancer Dose-Response Assessment and Application to Environmental Mixtures", Wash.D.C. U.S.EPA, 1996 [EPA/600/P-96/001F], at pp. 10-19

The animal studies plaintiffs' experts relied upon were not indicative of a link between PCB exposure and Joiner's type of cancer because the conditions of the mice (huge doses, direct injection, use of initiator chemicals) were not similar to the nature of Joiner's exposure - his "dose" was far smaller, and plaintiffs' experts have not identified an "initiator". Those tests did not mimic human exposures.

The District Court was correct in rejecting these contrived experiments as evidence that bears on Mr. Joiner's cancer.

Thus, plaintiffs admitted that there were no studies that showed that PCBs caused small-cell lung cancer in humans; referred to several epidemiological studies that were preliminary, equivocal, inconclusive at best and generally reflected no causal relationship between PCBs and Joiner's illness; and relied heavily on two mouse studies which were methodologically flawed and bore no basis in scientific fact to Joiner's exposure to PCBs and his disease.

Plaintiffs' experts failed to bridge the analytical gap between the available data and their conclusion that PCBs cause or promote small-cell lung cancer in humans. Because they failed to bridge that gap the district court correctly refused to admit their testimony.³ *See, Turpin v. Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349, 1360-61 (6th Cir.1992), *cert. denied*, 506 U.S. 826, 113 S.Ct. 84, 121 L.Ed.2d 47 (1992). (Regarding animal studies used to show the cause of birth defects, the court found "[t]he analytical gap between the evidence presented and the inferences to be drawn on the ultimate issue ... is too wide. Under such circumstances, a jury should not be asked to speculate on the issue of causation.").

Amici submit that plaintiffs' experts used flawed methodology. They were very selective in what they based their opinions on and ignored the facts of the case. The mice

³The dissenting judge in the Court of Appeals correctly observed that: "It is incumbent on the proponent of scientific evidence to fill the analytical gap between a proffered study and the particular facts of the case," citing to *Daubert* as support for that proposition.

studies which they primarily relied on (they admitted there were no human studies showing any causal relationship between PCBs and small-cell lung cancer) did not fit the facts of this case.

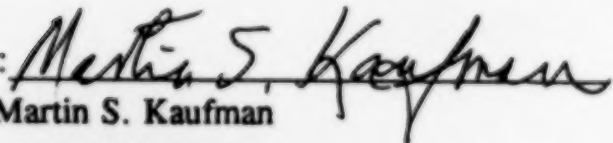
CONCLUSION

We submit that the District Court acted correctly because the methodology used by the Plaintiffs' experts was not scientific. Plaintiffs' experts failed to show that there is a connection between human exposure to PCBs and lung cancer. They failed to show that there is convincing animal evidence that PCBs can cause lung cancer. They offered no scientific methodology or arguments, buttressed by any reasonable review of the available evidence and data that indicate that Mr. Joiner's disease was associated with his occupational exposures. The method used by the plaintiffs' experts' selection of data favorable to their hypotheses while ignoring the overwhelming information that points away from it is not scientific and therefore the "evidence" upon which it is based is not reliable.

For the reasons stated above, we believe that the Supreme Court should reverse the decision of the Court of Appeals for the Eleventh Circuit and reinstate the decision of the District Court.

Dated: May 29, 1997

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